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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,854	02/18/2004	Toshihide Ezoe	Q79759	9456

23373 7590 06/12/2007

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EXAMINER	
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ART UNIT	PAPER NUMBER
1709	

MAIL DATE	DELIVERY MODE
06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,854	EZOE ET AL.	
	Examiner	Art Unit	
	Bobby Ramdhanie, Ph.D.	1709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *34-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/18/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1-33 are drawn to a biosensor, classified in class 436, subclass 173.

II. Claims 34-40, are drawn to a measurement chip, classified in class 436, subclass 532.

1. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the waveguide can be made out of a non-metal film(s) with a hydrophilic polymer. The subcombination has a separate utility for use as an anti-reflective coating(s) and hydrophobic coating(s) combinations used on eyeglasses to prevent glare and water streaks.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim

that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

1. During a telephone conversation with Mr. Brett Sylvester on 05/07/07, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-33. Affirmation of this election must be made by applicant in replying

to this Office action. Claims 34-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1-5, 12-20, & 22-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al (US 6329209). Regarding Claim 1, Wagner et al teaches a biosensor comprising a substrate coated with a hydrophobic polymer (Column 2, lines 63-67). Examiner takes the position that an organic thin film as disclosed is a hydrophobic polymer.

3. For Claim 2, Wagner et al, teaches a biosensor according to claim 1, wherein the metal surface or metal film coated with a hydrophobic polymer (Column 2 lines 63-67 and Column 13, lines 60-67).

4. For Claim 3, Wagner et al teaches a biosensor according to claim 2, wherein the metal surface or metal film comprises a free electron metal selected from a group consisting of gold, silver, copper, platinum, and aluminum (Column 13, lines 60-67).

5. For Claims 4 and 5, Wagner et al teaches a biosensor according to claim 1 wherein the coating thickness of the hydrophobic polymer is between 1-5000Å, and 10-2000 Å (Column 2 lines 63-67, Column 13 lines 60-67, and Column 7 lines 55-63).

6. For Claim 12, Wagner et al teaches a biosensor according to claim 1, which has a functional group capable of immobilizing a physiologically active substance on the outermost surface of the substance (Column 2 line 63-67; Column 3 lines 1-10).

7. For Claim 13, Wagner et al teaches a biosensor according to Claim 12 (Column 2 line 63-67; Column 3 lines 1-10), wherein the functional groups capable of immobilizing a physiologically active substance is –OH, -SH, -COOH, $-NR^1R^2$ (wherein each R^1 and R^2 independently represents a hydrogen atom or a lower alkyl group), -CHO, $NR^3NR^1R^2$ (wherein each of R^1, R^2, and R^3 independently represents a hydrogen atom or lower alkyl group), -NCO, -NCS, an epoxy group, or a vinyl group) (Column 19; lines 25-67).

8. For Claim 14, Wagner et al teaches a biosensor according to claim 12 (Column 2 line 63-67; Column 3 lines 1-10), which comprises a substrate coated with a hydrophobic polymer, and wherein a functional group capable of immobilizing a physiologically active substance by covalent bond (Column 9;

lines 25-30) is introduced in a hydrophobic polymer by chemical treatment of the surface of said substrate (Column 20; lines 43-50). Examiner takes the position that in order to have crosslinking, chemical treatment must be done to the surface of the film for the films to adhere to one another.

9. For Claim 15, Wagner et al teaches a biosensor according to claim 1 which comprises a linker for immobilizing a physiologically active substance on a surface of the biosensor (Column 2 lines 63-67, Column 3 lines 1-10, and Column 4 lines 47-51, Column 15 lines 47-67).

10. For Claims 16 and 17, Wagner et al teaches a biosensor according to claim 15 (Column 2 lines 63-67, Column 3 lines 1-10, and Column 4 lines 47-51, Column 15 lines 47-67) wherein the linker is a linker for immobilizing a physiologically active substance on the surface of the biosensor by chemical and covalent bonding (Column 2 lines 63-67, Column 3 lines 1-10, Column 4 lines 64-67, and Column 19 lines 16-21). Examiner takes the position that covalent bonding is the form of chemical bonding.

11. For Claim 18, The biosensor according to claim 15 (Column 2 lines 63-67, Column 3 lines 1-10, and Column 4 lines 47-51, Column 15 lines 47-67), wherein the linker is a compound represented by the formula (1)

X-L-Y...formula (1)

Wherein X represents a group capable of reacting with a functional group of a hydrophobic polymer, L represents a bivalent linking group, and Y represents a group capable of immobilizing a physiologically active substance (Column 15 lines 45-67).

12. For Claim 19, Wagner et al teaches a biosensor according to Claim 18 wherein the total number of atoms of L of the Formula (1) is 2 to 1000. (Column 17 lines 55-67)

13. For Claim 20, Wagner et al teaches a biosensor according to claim 1, which is used in non-electrochemical detection (Column 2 lines 57-67 and Column 3 lines 1-10).

14. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al. Wagner et al teaches a method for producing the biosensor according to Claim 1, which comprises a step of coating a substrate with a hydrophobic polymer (Column 7 lines 57-61, Column 8 lines 47-58, and Column 9 lines 26-29).

15. Claim 23, is rejected under 35 U.S.C. 102 (b) as being anticipated by Wagner et al. Wagner et al teaches a method for producing a biosensor according to claim 22, which further comprises a step of performing chemical treatment of a surface of the substrate (Column 7 lines 57-61, Column 8 lines 47-58, Column 9 lines 26-29, and Examples 1 & 4).

16. Claim 24, is rejected under 35 U.S.C. 102 (b) as being anticipated by Wagner et al. Wagner et al teaches a method for producing a biosensor according to Claim 22, which further comprises a step of reacting the substrate with a hydrophobic polymer with a linker (Column 7 lines 57-61, Column 8 lines 47-58, Column 9 lines 26-29, Column 16 lines 29-45, and Examples 1 & 4).

17. Claim 25, is rejected under 35 U.S.C. 102 (b) as being anticipated by Wagner et al. Wagner et al teaches a method for producing a biosensor

according to Claim 1, wherein a physiologically active substance is bound to the surface by covalent bonding (Column 2 lines 63-67, Column 3 lines 1-10, and Column 4 lines 64-67). Examiner takes the position that photo-crosslinking is a form of covalent bonding.

18. Claim 26, is rejected under 35 U.S.C. 102 (b) as being anticipated by Wagner et al. Wagner et al teaches a method for producing a biosensor according to Claim 1, which comprises a step of making said biosensor come in contact with said physiologically active substance, so that said physiologically active substance is bound to the surface by covalent bonding (Column 7 lines 57-61, Column 8 lines 47-58, Column 9 lines 26-29).

19. Claim 27, is rejected under 35 U.S.C. 102 (b) as being anticipated by Wagner et al. Wagner et al teaches a method for producing a biosensor according to Claim 1, to the surface of which comprises a step of making the biosensor according to claim 1, to the surface of which said physiologically active substance is bound by covalent bonding (Column 7 lines 57-61, Column 8 lines 47-58, Column 9 lines 26-29), come in contact with a test substance (Column 9 lines 58-67 and Column 10 lines 1-12).

20. Claim 28, is rejected under 35 U.S.C. 102 (b) as being anticipated by Wagner et al. Wagner et al teaches a method according to Claim 27, wherein a substance interacting with the physiologically active substance is detected or measured by a non-electrochemical method (Example 5 and Column 34 lines 2-9).

21. Claim 29, is rejected under 35 U.S.C. 102 (b) as being anticipated by Wagner et al. Wagner et al teaches a method according to Claim 27, wherein the physiologically active substance is detected or measured by surface plasmon resonance analysis (Example 5 and Column 34 lines 2-9).

22. Claims 1, 2, 6, 7 & 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al (US 5476094). Regarding Claim 1, Allen et al teaches a biosensor comprising a substrate coated with a hydrophobic polymer (Column 2 lines 64-67).

23. For Claim 2, Allen et al teaches a biosensor according to Claim 1, which comprises a metal surface or metal film coated with a hydrophobic polymer (Column 9 lines 3-11 Examiner takes the position that the electrodes need to be inherently electrically conductive – a metal substrate or a metal film).

24. For Claim 6, Allen et al teaches a biosensor comprising a substrate coated with a film whose swelling degree in pure water at 25°C is between 1 and 5 with respect to the film thickness in the dry state (Column 1 lines 10-15, Column 2 lines 64-67, Column 3 lines 1-5, & Claim 1).

25. For Claim 7, Allen et al teaches a biosensor according to Claim 6, wherein the film whose swelling degree in pure water at 25°C is between 1 and 5 with respect to the film thickness in a dry state is an organic substance (Column 1, lines 10-15, Column 2 lines 64-67, Column 3 lines 1-5, & Claim 1).

26. For Claim 9, Allen et al teaches the biosensor of Claim 6, wherein the film whose swelling degree in pure water at 25°C is between 1 and 5 with respect to

the film thickness in a dry state comprises a hardening agent (Column 1, lines 10-15, Column 2 lines 64-67, Column 3 lines 0-5, Claim 1, & Example 1).

27. Claims 1, 2, 3, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu (US 5273788). Yu teaches the biosensor of Claims 1, 2, & 3 (Column 4 lines 19-21) which is used for surface plasmon resonance (Abstract, Column 7 lines 1-5).

Claim Rejections - 35 USC § 103

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

29. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

30. Claims 10 & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al in further view of Wagner et al. Regarding Claim 10, Allen et al teaches a biosensor according to Claim 6 which comprises a film whose swelling degree in pure water at 25 °C is between 1 and 5 with respect to

the film thickness in a dry state. Allen et al does not teach the film coating to be on the metal surface or metal film. Wagner et al teaches a biosensor comprising a metal or metal film coated with a hydrophobic polymer. It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify Allen et al with Wagner et al because according to Allen et al, the acrylic copolymers are effective, for example in controlling the diffusion of analytes/reactants to a covered biosensor (Column 6 lines 47-50).

31. For Claim 11, Allen et al teaches a biosensor according to Claim 6. Allen et al does not teach that the biosensor comprises a metal or metal film comprising a free electron metal selected from a group consisting of gold, silver, copper, platinum or aluminum. Wagner et al teaches a biosensor comprising a metal or metal film comprising a free electron metal selected from a group consisting of gold, silver, copper, platinum or aluminum (Column 14, lines 29-36). It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify Allen et al with Wagner et al because according to Allen et al, the acrylic copolymers are effective, for example in controlling the diffusion of analytes/reactants to a covered biosensor.

32. Claims 30-33 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Wagner et al in further view of Targoz (US 5346725). Regarding Claim 30, Wagner et al teaches a method for detecting or measuring a substance intereacting with a physiologically active substance which is bound to the surface of a biosensor comprising a substrate coated with a hydrophobic polymer (Claims 1 & 2). Wagner et al does not teach a method where the above detection

or measurement is carried out in the presence of a surfactant. Targoz teaches hydrophobic polymer which contains a surfactant (Abstract). It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify Wagner et al with Targoz because according to Targoz, the addition of the surfactant to the hydrophobic polymer aids in helping the polymer attach to the substrate (Abstract).

33. For Claim 31, Wagner et al teaches a method for detecting or measuring a substance interacting with a physiologically active substance which is bound to the surface of a biosensor comprising a substrate coated with a hydrophobic polymer (Claims 1 & 2). Wagner et al does not teach a method where the above detection or measurement is carried out in the presence of a surfactant which is nonionic. Targoz teaches the use of a nonionic surfactant FC-170C for use with a hydrophobic polymer (Column 7 lines 34-41). It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify Wagner et al with Targoz because according to Targoz, the addition of the surfactant to the hydrophobic polymer aids in helping the polymer attach to the substrate (Abstract).

34. For Claim 32, Wagner et al teaches a method for detecting or measuring a substance interacting with a physiologically active substance which is bound to the surface of a biosensor comprising a substrate coated with a hydrophobic polymer (Claims 1 & 2). Wagner et al also teaches a method wherein a solution containing at least a test substance is allowed to come in contact with a biosensor comprising a substrate coated with a hydrophobic polymer, on the

surface of which a physiologically active substance is bound by covalent bonding. Wagner et al does not teach a solution containing a surfactant that comes in contact with the hydrophobic polymer and substrate. Targoz teaches a step for enhancing the film properties using a test substance and a surfactant in a solution to be applied to the hydrophobic polymer and substrate (Claim 7). It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify Wagner et al with Targoz because according to Targoz, the addition of the surfactant to the hydrophobic polymer aids in helping the polymer attach to the substrate (Abstract).

35. For Claim 33, Wagner et al teaches a method for detecting or measuring a substance interacting with a physiologically active substance which is bound to the surface of a biosensor comprising a substrate coated with a hydrophobic polymer (Claims 1 & 2). Wagner et al also teaches a method wherein a solution containing at least a test substance is allowed to come in contact with a biosensor comprising a substrate coated with a hydrophobic polymer, on the surface of which a physiologically active substance is bound by covalent bonding. Wagner et al neither teaches a solution containing a surfactant that comes in contact with the hydrophobic polymer and substrate nor does Wagner et al teach a method where the surfactant is between 0.0001-1% by weight. Targoz teaches a step for enhancing the film properties using a test substance and a surfactant in a solution to be applied to the hydrophobic polymer and substrate which is within 0.01-2% (Claim 7). It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify Wagner et

al with Targoz because according to Targoz, the addition of the surfactant to the hydrophobic polymer aids in helping the polymer attach to the substrate (Abstract).

Claim Rejections - 35 USC § 112

36. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

37. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding Claims 1-29, Claims 1-29 do not distinctly point out whether the substrate of the biosensor is coated on one side or both sides with a hydrophobic polymer.

38. Claims 15-17 do not distinctly point out whether the linker is attached to the polymer-free side of the substrate, to the hydrophobic polymer side (in the cases where the substrate is only coated on one side) or to a hydrophobic polymer surface that completely encases both sides of the substrate of the biosensor.

39. Claim 25 does not distinctly point out which surface of the biosensor the physiologically active substance is bound to via covalent bonding.

Allowable Subject Matter

40. Claim 8 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not disclose or suggest a biosensor wherein the film comprises a high polymer with the claimed characteristics.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Ramdhanie, Ph.D. whose telephone number is 571-270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter D. Griffin

WALTER D. GRIFFIN
SUPERVISORY PATENT EXAMINER